fluid from within the duct for analysis, and wherein said probe is free of a connection for a fluid source or lumen.

a1

2. (Amended) A device as in claim 1, wherein the distal portion comprises an absorbent material that can absorb the breast duct fluid.

Please add new claims 26 and 27 as follows.

26. Advice as in claim 1, wherein said diameter of said probe is between about 0.008 cm and about 0.040 cm.

a2

27. A device a in claim 26, wherein said diameter of said probe is between about 0.012 cm and about 0.025 cm.

REMARKS

The Office Action of July 18, 2002 has been received and considered. In the Office Action, a written copy of the oral Restriction was provided. Also, the claims were rejected under either 35 U.S.C. §102(b) or under 35 U.S.C. §103(a) based on U.S. Patent No. 4,635,488 to Kremer, alone or in combination with other publications.

Claim 1 has been amended. Claims 14-25 have been cancelled. Claims 26 and 27 have been added. Currently, claims 1-13, 26 and 27 are pending.

The amendments to claim 1 have not been made to overcome any rejection or prior art. Instead, these amendments were made to rephrase portions of this claim and further enhance its clarity. The amendment to claim 2 was made to cure a typographical omission.

An aspect of the present invention relates to a device that is introduced into a breast duct in order to obtain a ductal fluid sample from within the duct. The device has a diameter that is

sized to allow the device to enter the breast duct, contact the epithelial lining of the duct and collect fluid from within the breast duct. As is well known, the diameter of a ductal opening is extremely small and is difficult, if not impossible for some, to see with the naked eye. As discussed in the specification, the diameter of the device can be between about 0.008cm and about 0.040cm so that it can enter the ductal opening, pass the ductal sphincter and establish communication with the portion of the breast duct that contains the ductal fluid.

Claims 1-7 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,635,488 to Kremer that discloses a device for nonintrusively collecting fluid from a body. These fluids include sweat, tears and saliva. The device includes an open ended tube and a sample-collecting nib mounted in the open end. The patent to Kremer does not disclose or suggest that the device is used to collect breast duct fluid.

As recited in claim 1, the device according to the present invention is sized to be positioned within a breast duct and retrieve ductal fluid from within the duct. Clearly, the device disclosed in the patent to Kremer is not sized to fit within a ductal opening. Thus, contrary to the position taken in the Office Action, Kremer does not disclose a device (1) that is sized to fit within a breast duct, (2) that is capable of being positioned within a breast duct or (3) that is intended to collect ductal fluid samples from within a breast duct. As a result, the patent to Kremer does not disclose the device recited in claim 1. Withdrawal of the rejection is requested.

Applicant also submits that it would not have been obvious to modify the Kremer device to arrive at the device recited in claim 1 because the patent to Kremer expressly discloses that the Kremer device is for nonintrusive fluid collection.

As is well known, a breast duct includes a sphincter located at a position spaced between its fluid retaining portion and its ductal opening. This sphincter prevents ductal fluid from unintentionally exiting the breast duct. Thus, in order to obtain fluid from within the duct, a tool must overcome the strength of the sphincter, pass through the sphincter and enter the fluid containing portion of the duct. Applicants submit that placing a tool within a duct so that it over powers and passes through the ducal sphincter is clearly an intrusive procedure. Therefore, it would not have been obvious to modify the nonintrusive fluid collection device of Kremer to be sized to fit within a breast duct or to collect ductal fluid from within a breast because such collection is clearly intrusive and thus contradicts the disclosure of Kremer. Moreover, the use of the Kremer device would not have been obvious because the discontinuous transition between the nib and the open-ended tube of the Kremer device would damage the ductal sphincter or the epithelial lining of a duct, thereby rupturing the duct.

Claims 8 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kremer in view of U.S. Patent No. 6,413,228 to Hung et al. The Hung disclosure is relied upon to disclose that ductal fluids comprise indicia and markers. It was asserted that it would have been obvious to modify the fluid collecting device of Kremer to include means for detecting the quality of the ductal fluid based on the teaching of the Hung disclosure.

As discussed above, the device of Kremer is not sized to fit within a ductal fluid opening. Additionally, the device disclosed in the patent to Kremer is not used to collect or otherwise sample ductal fluid.

The patent to Hung fails to disclose the device recited in claim 1. While the patent to Hung does disclose a device that is sized for inserting within a breast duct, this device includes a centrally disposed lumen and at least one port for connecting the device to a fluid source. Consequently, the patent to Hung does not disclose a device that is (1) free of a connection intended for use with a fluid source or a lumen and (2) sized for positioning within a duct and sampling ductal fluid. Therefore, nothing in the disclosure of Hung would have motivated one of ordinary skill in the art to modify the device of Kremer to arrive at the ductal fluid collection device recited in the pending claims. Withdrawal of the rejection is requested.

Claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kremer in view of U.S. Patent No. 5,844,251 to MacDonald et al. MacDonald is relied upon to disclose a probe comprising MEMS. It was asserted that it would have been obvious to modify the fluid collecting device of Kremer to create a probe with a MEMS that is used to scan surfaces of a breast duct in order to measure surface configurations on a micron scale. However, like Hung, MacDonald does not teach what Kremer lacks.

As discussed above, the device of Kremer is not sized to fit within a ductal fluid opening. Additionally, the device disclosed in the patent to Kremer is not used to collect or otherwise sample ductal fluid. MacDonald does not disclose a device that is sized for fitting within a breast duct, that samples ductal fluid and that is free from a connection to a fluid source as recited in claim 1. Therefore, nothing in the disclosure of MacDonald would have motivated one of ordinary skill in the art to modify the device of Kremer to arrive at the ductal fluid collection device recited in the pending claims. Withdrawal of the rejection is requested.

Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kremer in view of U.S. Patent No. 5,263,926 to Wilk. The Wilk disclosure is relied upon to teach a probe with an externally applied anesthetic. It was asserted that it would have been obvious to modify the fluid collecting device of Kremer to include an externally carried anesthetic. However, Applicant submits that the use of an anesthetic would be contrary to the purpose of the Kremer collection device.

The collection device of Kremer is not sized to fit within a ductal fluid opening as discussed above. Additionally, Kremer expressly discloses that his device is used in a nonintrusive manner to collect sweat and saliva from the body. Clearly, the collection of these fluids does not require the use of an anesthetic. In fact, the use of an anesthetic in these instances would be unnecessary and possibly dangerous. Moreover, the patent to Wilk does not teach a fluid collection device sized to fit within a breast duct. Therefore, the disclosure of Wilk would not have motivated one of ordinary skill in the art to modify the device of Kremer to arrive at the ductal fluid collection device recited in the pending claims. Withdrawal of the rejection is requested.

Claims 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kremer in view of U.S. Patent No. 5,382,228 to Nita et al. The Nita patent is relied upon to disclose the use of shape memory materials. However, this patent only discloses the use of shape memory materials for an ultrasonic probe. It was asserted that it would have been obvious to modify the fluid collecting device of Kremer to include the shape memory material of the ultrasonic transmitting wire disclosed in the patent to Nita.

The patent to Nita does not disclose a fluid collection device as recited. Moreover, this patent is not analogous art to the device of Kremer. The device disclosed in the patent to Nita is a catheter used in invasive, ultrasonic procedures to remove obstructions within blood vessels – a function completely unrelated to the collection of fluids from an external body surface. Applicant submits that one of ordinary skill in the art of collecting externally disposed bodily fluids would not have looked to the teachings of internally positioned ultrasonic probes, such as the one disclosed in the patent to Nita.

Additionally, as discussed above, the patent to Nita fails to disclose a fluid collecting device as recited in claim 1. Moreover, Nita fails to disclose a fluid collection device that is rigid before entering a duct and flexible after its introduction. Therefore, nothing in the disclosure of Nita would have motivated one of ordinary skill in the art to modify the device of Kremer to arrive at the ductal fluid collection device recited in the pending claims. Withdrawal of the rejection is requested.

For all of the above-discussed reasons, claims 1-13, 26 and 27 are allowable over the prior art. Applicant respectfully submits that the application is now in condition for allowance. A notice to this effect is earnestly solicited.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicant's attorney, the Examiner is invited to contact Applicant's attorney at the number noted below.

Respectfully submitted,

Dated: October 4, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A device for collecting[on of] breast duct fluid from within a breast duct [and detection of] in order to detect breast cancer or precancer comprising:

a probe [of] having a diameter [sufficiently small] sized to penetrate a breast duct and [having] a distal portion being capable of contacting an interior lumen of a breast duct[, wherein said distal portion] and retrieving a [can contact and retrieve a sufficient] sample of the breast duct fluid from within the duct for analysis, and wherein said probe [unattached] is free of a connection for [to] a fluid source or lumen.

2. (Amended) A device as in claim 1, wherein the distal portion comprises an absorbent material that can absorb the breast duct fluid.